U.S. Application No.: 10/622,736

**AMENDMENTS TO THE CLAIMS** 

This listing of claims will replace all prior versions and listings of claims in the

application:

**LISTING OF CLAIMS:** 

1. (currently amended): A reagent kit for detecting lupus anticoagulant in blood, said kit

comprising:

a first coagulation time reagent containing phospholipids including phosphatidylserine;

and

a second coagulation time reagent containing phospholipids including phosphatidylserine

wherein the content of phosphatidylserine to the total content of the phospholipids in the

first coagulation time reagent is different from the content of phosphatidylserine to the total

content of the phospholipids in the second coagulation time reagent, and wherein the lupus

anticoagulant is detected based on a first coagulation time obtained by using the first coagulation

time reagent and a second coagulation time obtained by using the second coagulation time

reagent.

2. (original): The reagent kit of claim 1, wherein the concentration of phosphatidylserine

in a mixture of a sample and the first coagulation time reagent ranges from 10 μ g/ml to 30 μ

g/ml 10 μg/ml to 30 μg/ml, and the concentration of phosphatidylserine in a mixture of a sample

and the second coagulation time reagent ranges from  $\frac{1 \mu g/m}{to 7 \mu g/ml} \mu g/ml$  to  $\frac{7 \mu g/ml}{to 7 \mu g/ml}$ .

2

U.S. Application No.: 10/622,736

3. (original): The reagent kit of claim 1, wherein a concentration of phosphatidylserine in the first coagulation time reagent is 10 to 20 times as high as a concentration of phosphatidylserine in the second coagulation time reagent.

- 4. (original): The reagent kit of claim 2, wherein a concentration of phosphatidylserine in the first coagulation time reagent is 10 to 20 times as high as a concentration of phosphatidylserine in the second coagulation time reagent.
- 5. (original): The reagent kit of claim 2, wherein the concentration of phosphatidylserine in a mixture of a sample and the first coagulation time reagent ranges from  $\frac{15 \mu g/m}{15 \mu g/m}$  and the concentration of phosphatidylserine in a mixture of a sample and the second coagulation time reagent ranges from  $\frac{2 \mu g/ml}{15 \mu g/ml}$   $\frac{2 \mu g/ml}{15 \mu g/ml}$   $\frac{2 \mu g/ml}{15 \mu g/ml}$ .
- 6. (original): The reagent kit of claim 1 wherein the phosphatidylserine is synthetic phosphatidylserine or at least 99% purified phosphatidylserine derived from natural resources.
- 7. (original): The reagent kit of claim 1, wherein each of the first and the second coagulation time reagent further contains an activator and calcium ions.

U.S. Application No.: 10/622,736

8. (currently amended): The A reagent kit of claim-1, wherein the first coagulation time reagent comprises a first preparatory reagent and a second preparatory reagent, and the second coagulation time reagent comprises a third preparatory reagent and a fourth preparatory reagent,

wherein the first reagent for detecting lupus anticoagulant in blood, said kit comprising:

a first preparatory reagent contains containing phospholipids including

phosphatidylserine, the concentration of the phosphatidylserine in the first preparatory reagent ranges from 3 μ g/ml to 1000 μ g/ml 3 μg/ml to 1000 g/ml;

a second reagent containing calcium ions;

the <u>a</u> third preparatory reagent contains phospholipids including phosphatidylserine, the concentration of the phosphatidylserine in the third preparatory reagent ranges from  $0.2 \mu \text{ g/ml}$  to  $200 \mu \text{ g/ml}$  to  $200 \mu \text{ g/ml}$ ; and

a fourth reagent containing calcium ions;

wherein the content of phosphatidylserine to the total content of the phospholipids in the first reagent is different from the content of phosphatidylserine to the total content of the phospholipids in the third reagent,

wherein the concentration of the phosphatidylserine in the first preparatory reagent is higher than that of the phosphatidylserine in the third preparatory reagent, and

wherein the lupus anticoagulant is detected based on a first coagulation time obtained by using the first and second reagents, and a second coagulation time obtained by using the third and fourth reagents.

U.S. Application No.: 10/622,736

9. (currently amended): The reagent kit of claim 8, wherein the concentration of the phosphatidylserine in the first preparatory reagent ranges from  $30 \mu$  g/ml to  $100 \mu$ g/ml.

- 10. (currently amended): The reagent kit of claim 8, wherein the concentrations of the phosphatidylserine in the third preparatory reagent ranges from  $2 \mu \text{ g/ml}$  to  $20 \mu \text{ g/ml}$  to  $20 \mu \text{ g/ml}$ .
- 11. (currently amended): The reagent kit of claim 8, wherein each of the first and the third <del>preparatory</del> reagents further contains phosphatidylethanolamine and phosphatidylcholine.
- 12. (currently amended): The reagent kit of claim 11, wherein the concentration of the phosphatidylethanolamine in each of the first and third preparatory reagents ranges from  $0.1~\mu$  g/ml to 300  $\mu$  g/ml to 300  $\mu$ g/ml, and the concentration of the phosphatidylcholine in each of the first and third preparatory reagents ranges from  $2~\mu$  g/ml to  $1000~\mu$ g/ml.
- 13. (currently amended): The reagent kit of claim 11, wherein the concentration of the phosphatidylethanolamine in each of the first and third preparatory reagents ranges from  $1 \mu$  g/ml to 30  $\mu$  g/ml to 30  $\mu$ g/ml, and the concentration of the phosphatidylcholine in each

U.S. Application No.: 10/622,736

of the first and third <del>preparatory</del> reagents ranges from 20 μ g/ml to 100 μ g/ml 20 μg/ml to 100

<u>μg/ml</u>.

14. (currently amended): The reagent kit of claim 8, wherein each of the first and the

third preparatory reagents further contains phosphatidylethanolamine, phosphatidylcholine and

an activator; and

each of the second and the fourth preparatory reagents contains calcium ions.

15. (original): The reagent kit of claim 14, wherein the activator is at least one selected

from the group consisting of ellagic acid, kaolin, and sellaite.

16. (original): The reagent kit of claim 1, wherein each of the first and the second

coagulation time reagents further contains a viper venom and calcium ions.

17. (original): The reagent kit of claim 1, wherein each of the first and the second

coagulation time reagents further contains phosphatidylethanolamine, phosphatidylcholine, viper

venom and calcium ions.

18. (original): The reagent kit of claim 16, wherein the viper venom is at least one

selected from the group consisting of Russel's venom, textarin venom and ecarin venom.

6

U.S. Application No.: 10/622,736

19. (original): The reagent kit of claim 1, wherein each of the first and the second coagulation time reagents further contains a tissue factor and calcium ions.

20. (original): The reagent kit of claim 1, wherein each of the first and the second coagulation time reagents further contains phosphatidylethanolamine, phosphatidyletholine, a tissue factor and calcium ions.

21. (new): A reagent kit for detecting lupus anticoagulant in blood, said kit comprising:

a first reagent containing phospholipids including phosphatidylserine, the concentration of the phosphatidylserine in the first reagent ranging from 30 µg/ml to 1000 µg/ml;

a second reagent containing calcium ions;

a third reagent containing phospholipids including phosphatidylserine, the concentration of the phosphatidylserine in the third reagent ranging from 0.2  $\mu$ g/ml to 20  $\mu$ g/ml; and

a fourth reagent containing calcium ions;

wherein the lupus anticoagulant is detected based on a first coagulation time obtained by using the first and second reagents, and a second coagulation time obtained by using the third and fourth reagents.

22. (new): A method for detecting lupus anticoagulant in blood comprising:

a step of comparing a first coagulation time measured by use of a first coagulation time reagent containing phospholipids including phosphatidylserine with a second coagulation time

U.S. Application No.: 10/622,736

measured by use of a second coagulation time reagent containing phospholipids including phosphatidylserine, wherein the content of phosphatidylserine to the total content of the phospholipids in the first coagulation time reagent is different from the content of phosphatidylserine to the total content of the phospholipids in the second coagulation time reagent, and

a step of detecting lupus anticoagulant in blood based on the result obtained from the comparing step.

23. (new): A method for detecting lupus anticoagulant in blood comprising:

a step of comparing a first coagulation time measured by use of a first reagent containing phospholipids including phosphatidylserine and a second reagent containing calcium ions, with a second coagulation time measured by use of a third containing phospholipids including phosphatidylserine and fourth reagent containing calcium ions, and

a step of detecting lupus anticoagulant in blood based on the result obtained from the comparing step,

wherein the concentration of the phosphatidylserine in the first reagent ranges from 3 ug/ml to 1000 μg/ml, the concentration of the phosphatidylserine in the third reagent ranges from 0.2 µg/ml to 200 µg/ml, wherein the content of phosphatidylserine to the total content of the phospholipids in the first reagent is different from the content of phosphatidylserine to the total content of the phospholipids in the third reagent, and wherein the concentration of the

8

AMENDMENT UNDER 37 C.F.R. § 1.111

U.S. Application No.: 10/622,736

Attorney Docket No.: Q76592

phosphatidylserine in the first reagent is higher than that of the phosphatidylserine in the third reagent.